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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,255	08/20/2002	David Wallach	WALLACH=28	2930

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,255	WALLACH ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *14-29,31,32 and 34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1 in the reply filed on 11 October 2005 is acknowledged. Applicants have indicated confusion at the grouping of the claims. The office regrets any inadvertent confusion caused by the language used in the restriction. Applicants assert that "Group 1 and Group 4 appear to be directed to DNA sequences encoding the protein IREN. Group 4 refers to a DNA sequence as depicted in Figure 6, while Figure 6 has no DNA sequence." Regarding the latter, Group 4 claims "A DNA sequence... comprising at least part of the sequence depicted in Fig. 6". Since the second occurrence of the word "sequence" has no other antecedent basis other than the DNA sequence, the confusion derives in large part from the claim language itself.

Regarding the former point is that Group 1 and Group 4 appear to be directed to DNA sequences encoding the protein IREN, these two groups are hereby rejoined, since it is now apparent that applicants attempts were to claim the IREN sequence as specifically recited in figure 3, as well as any DNA sequence encoding the IREN polypeptide of figure 6, because these two groups are considered to possess unity of invention.

The remainder of applicants' arguments regarding rejoinder of those groups other than Groups 1 and 4 are not considered convincing. In addition to the groups lacking unity for the reasons previously set forth in the restriction requirement mailed 9 August 2005, broad claim 1, directed to various embodiments of the IREN cDNA sequence and its splice variants, is also considered to lack unity of invention in view of SEQ ID NO: 1 of Wallach et al. (WO 97/37016). The sequence listed therein is considered to at least

meet the qualifications of claim 1, step (d), a fragment of a sequence of (a)-(c) which encodes a biologically active protein capable of binding to at least the 225-501 amino acid sequence of TRAF2. It is noted, that had lack of unity not been cited in view of this art, that Groups 2 and 6 would be rejoined as would Groups 5 and 7. However since unity of invention is considered to be lacking in view of the Wallach reference, the issue is considered moot.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-29, 31, 32, 34-44, and the subject matter of claims 1-13, 30 and 33 NOT drawn to the nucleotide sequence encoding IREN are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 October 2005.

Claim Objections

Claims 4, 5, 9-13, 30, and 33 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot form the basis for further clean dependencies. See MPEP § 608.01(n). Accordingly, the claims listed above have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The invention of claims 1-3 is drawn to a DNA sequence comprising the nucleotide sequence depicted in figure 3. The invention of claim 8 is drawn to a DNA sequence encoding polypeptide depicted in figure 6.

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances when there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See M.P.E.P. 608.01(m). Amendment to recite the sequence by SEQ ID NO: would be corrective.

Claims 7, and by dependency claim 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is drawn to a cDNA sequence derived from the coding region of a native IREN protein. The term "derived from" is considered to be indefinite, since one of skill in the art would not know that the metes and bounds of the claimed invention based on

the recitation of a starting product which is modified exclusively by the vague term "derived from".

Claim 7 is further indefinite because the claim recites "a cDNA sequence derived from the coding region of the native IREN protein". As Applicants are no doubt aware, a protein does not have a coding region; a cDNA has a coding region. Correction is required.

Claim 7 is further indefinite for the recitation of "moderately stringent conditions". Stringency is determined by several variable factors, such as temperature, salinity, and GC content. One of skill in the art could not be apprised of the metes and bounds of a claim reciting "moderately stringent conditions", since such variability exists, and no standard exists for the term "moderate".

Claim 7 element (b) is also indefinite because it is drawn to a sequence which is complementary to a sequence that encodes a biologically active IREN, yet which paradoxically, itself also encodes a biologically active IREN. Clarification is required.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is drawn to "a DNA sequence according to claim 6 or 7 comprising at least part of the sequence depicted in Fig. 6...". The claim is indefinite, because the sequence depicted in figure 6 is a polypeptide, and because one literal interpretation of the claim would have the DNA sequence comprising part of the polypeptide sequence of

figure 6. The metes and bounds of the claimed coverage cannot be determined and is thus indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to a cDNA sequence encoding the active protein IREN, or isoforms, fragments, or analogs thereof, or to cDNA sequences derived from the coding region of the native IREN protein or DNA sequences capable of hybridizing to such sequences, or degenerate sequences thereof, which encode a biologically active IREN.

At the outset it is noted that the rejected claims do not recite any sequence identifier relating to IREN. This sequence is thus considered to be defined by its function (i.e. the activity of IREN as disclosed in the specification and/or prior art) rather than by any one specific structure. Accordingly the claim embraces, or directly claims, any sequence of any IREN, genomic or transcribed, or any such molecule with analogous IREN activity, known or yet to be discovered, along with any isoform or allele present within any species, or any variant, polymorphic or otherwise, that is within reasonable

similarity from these families of proteins that retain IREN activity. The invention is also specifically is drawn to fragments that retain such IREN activity

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof. The representative sample requirement may be satisfied by supplying structural or functional information, or a combination of both, such that one of skill in the art would be satisfied that applicants were in possession of the genus as claimed. Further, the size of the representative sample required is an inverse function of the unpredictability of the art.

In order to possess the claimed invention, the specification and/or prior art would first need to provide a representative sample of sequences of IREN which is commensurate with the breadth of analogs fragments in derivatives described above. However, the only IREN cDNA sequence taught in the specification is that of SEQ ID NO: 4. While the specification also discloses cDNA sequence is relating to IREN-10B, and IREN-E, as well as their predicted polypeptide sequences, and also discloses which

half of such polypeptides are necessary for binding to TRAF2, this is not considered to provide enough structural detail such that one of skill in the art could envision a sufficient number of structures of the remainder of the representative sample of cDNA or polypeptide sequences that would have IREN like activity, let alone which fragments, isoforms, or analogs would have such activity. This is because this teaching does not fully characterize the various remaining domains which may be removed, altered, or point mutated such that IREN activity is retained. This is considered particularly critical for those claim elements drawn to fragments analogues or isoforms of IREN.

Regarding function, the specification teaches that the instant IREN protein can bind to TRAF2, but it is unlikely that this is the only function that IREN is capable of carrying out, particularly in view of the domains of the splice variants indicated in the exmaples. The prior art appears to be silent as to any structure or function of IREN. Thus, it is maintained that applicants have not provided a representative sample of the genus of any IREN structure, let alone fragments analogues or derivatives thereof that would have IREN like activity, particularly in light of the fact that it's only disclosed interaction is with that of TRAF2 and/or NF-KappaB.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach et al. (WO 97/37016).

The claims of the instant invention are drawn to a DNA sequence encoding the protein IREN, isoforms, fragments or analogs thereof, said IREN, isoforms, fragments or analogs thereof being capable of binding to TRAF2 and of modulating activity of NF-κB, as well as a cDNA sequence derived from the coding region of the native IREN protein, or a DNA sequence capable of hybridization to said coding region under moderately stringent conditions and which encodes a biologically active IREN, or the cDNA sequence which is degenerate to a biologically active IREN polynucleotide and which encodes a biologically active IREN protein, or a DNA sequence comprising at least part of the sequence depicted in figure 6, and encoding at least one active IREN protein, isoform, analog or fragment.

Wallach et al. teaches SEQ ID NO: 1, which is a polynucleotide sequence 1906 nucleotides long that shares 99.6% similarity over the entire 1782 nucleotides of the DNA sequence shown in figure 3 of the instant application. Therefore, Wallach et al. is considered to teach a cDNA sequence encoding at least an isoform of the protein IREN, and given that the homology is so high, it would also considered to bind to NF-KappaB.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JDS

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PATENT EXAMINER